NAME OF THE MEDICINAL PRODUCT

Midazolam B. Braun 1 mg/ml solution for injection/infusion
Midazolam B. Braun 5 mg/ml solution for injection/infusion

COMPOSITION

The emulsion for injection/infusion contains:

	Midazolam B. Braun 1 mg/ml	**Midazolam B. Braun 5 mg/ml**
1 ml	1 mg midazolam as 1.112 mg of midazolam hydrochloride	5 mg midazolam as 5.56 mg of midazolam hydrochloride
in 1 ampoule of 1 ml	-	5 mg midazolam as 5.56 mg of midazolam hydrochloride
in 1 ampoule of 3 ml	-	15 mg midazolam as 16.68 mg of midazolam hydrochloride
in 1 ampoule of 5 ml	5 mg midazolam as 5.56 mg of midazolam hydrochloride	-
in 1 ampoule of 10 ml	-	50 mg midazolam as 55.6 mg of midazolam hydrochloride
in 1 bottle of 50 ml	50 mg midazolam as 55.6 mg of midazolam hydrochloride	-
in 1 bottle of 100 ml	100 mg midazolam as 111.2 mg of midazolam hydrochloride	-

Excipient with known effect:
Midazolam B. Braun 1 mg/ml solution for injection: Sodium 3.5 mg/ml
Midazolam B. Braun 5 mg/ml solution for injection: Sodium 2.2 mg/ml

Excipients: Sodium chloride, hydrochloric acid 10 %, water for injections.

THERAPEUTIC INDICATIONS

Midazolam B. Braun is a short-acting sleep-inducing medicinal product that is indicated:

In adults:
Conscious sedation: Before and during diagnostic or therapeutic procedures with or without local anaesthesia.
General anaesthesia: Premedication before induction of general anaesthesia; induction of general anaesthesia; as a sedative component in combined anaesthesia.

Sedation in intensive care units.

In children:
Conscious sedation: Before and during diagnostic or therapeutic procedures with or without local anaesthesia.
General anaesthesia: Premedication before induction of general anaesthesia.
Sedation in intensive care units.

CONTRAINDICATIONS

Hypersensitivity to midazolam, benzodiazepines or to any of the excipients;
conscious sedation in patients with severe respiratory failure or acute respiratory depression.

UNDESIRABLE EFFECTS

Undesirable effects are listed according to their frequencies as follows:

Not known: (cannot be estimated from the available data)

The following undesirable effects have been reported (frequency not known, cannot be estimated from the available data) to occur when midazolam is injected:

Immune system disorders
Hypersensitivity, angioedema, anaphylactic shock

Psychiatric disorders
Confusional state, disorientation, emotional and mood disturbances, changes in libido, Agitation*, hostility*, anger*, aggressiveness*, excitement*.
Physical drug dependence and withdrawal syndrome, abuse.

Nervous system disorders
Sedation (prolonged and postoperative), alertness decreased, somnolence, headache, dizziness, ataxia, anterograde amnesia, the duration of which is directly related to the administered dose. Anterograde amnesia may still be present at the end of the procedure and in isolated cases prolonged amnesia has been reported.
Convulsions have been reported more frequently in premature infants and neonates.
Drug withdrawal convulsions.
Involuntary movements (including tonic/clonic movements and muscle tremor*), hyperactivity*.

Cardiac disorders
Cardiac arrest, bradycardia.

Vascular disorders
Hypotension, vasodilation, thrombophlebitis, thrombosis.

Respiratory, thoracic and mediastinal disorders
Respiratory depression, apnoea, respiratory arrest, dyspnoea, laryngospasm, hiccups.

Gastrointestinal disorders
Nausea, vomiting, constipation, dry mouth.

Skin and subcutaneous tissue disorders
Rash, urticaria, pruritus.

General disorders and administration site conditions
Fatigue, erythema and pain on injection site.

Injury, poisoning and procedural complications
Falls, fractures. The risk of falls and bone fractures is increased in patients taking sedatives concomitantly (including alcoholic beverages) and in elderly patients.

Social circumstances
Assault*.

*Such paradoxical drug reactions have been reported, particularly among children and the elderly.

Renal impairment: There is a greater likelihood of adverse drug reactions in patients with severe renal impairment.

Dependence: Use of midazolam – even in therapeutic doses – may lead to the development of physical dependence. After prolonged intravenous administration, discontinuation, especially abrupt discontinuation of the product, may be accompanied by withdrawal symptoms including withdrawal convulsions. Cases of abuse have been reported.

Severe cardio-respiratory adverse events have occurred. Life-threatening incidents are more likely to occur in adults over 60 years of age and those with pre-existing respiratory insufficiency or impaired cardiac function, particularly when the injection is given too rapidly or when a high dosage is administered

WARNINGS
Keep out of the sight and reach of children.

NOTE
Prescription only
Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

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